

K121630

SEP 11 2012

510(k) Summary  
for the  
Range Spinal System

This 510(k) summary for the Everest Spinal System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

**1. Submitter :**  
K2M, Inc.  
751 Miller Drive SE,  
Suite F1  
Leesburg, VA 20175

**Contact Person :**  
Nancy Giezen  
K2M, Inc..  
Telephone: 703-777-3155

**Date Prepared:** 06/01/12

**2. Tradename:** Range Spinal System  
**Common Name:** Spinal Fixation System  
**Classification Name:** Pedicle Screw Spinal System (21CFR 888.3070)  
**Device Product Code:** OSH, MNI, MNH, KWP  
**Regulatory Class:** Class II

**3. Predicate or legally marketed devices which are substantially equivalent :**

- Synthes USS (K994121, K082572)
- Paradigm Spine Orthobium (K071668)
- Medtronic CD Horizon (K091445, K102555, K102807, K110070, 111942, K111457, K111510, K112555, K112473, K113174, K113529)
- Orthopediatrics OP Spine System (K120291)

**4. Description of the device:**

The Range Spinal System is a top-loading, multiple component, posterior (thoracic-lumbar) spinal fixation system which consists of pedicle screws, rods, locking set screws, and hooks.

**Materials:** The devices are manufactured from Titanium Alloy and Cobalt Chrome per ASTM and ISO standards.

**Function:** The system functions as an adjunct to fusion to provide immobilization and stabilization of the posterior thoracic and lumbar spine.

**5. Purpose of Submission:**

The purpose of this submission is expand the indications for use to include the treatment of adolescent idiopathic scoliosis.

**6. Intended Use:**

RANGE/ DENALI/ MESA and ARI are cleared for the following indications:

Non-cervical, pedicle screw fixation devices for posterior stabilization as an adjunct to fusion for the following indications: trauma ( i.e. fracture or dislocation ); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis ( grades 3 and 4 ) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine ( L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Pg 1 of 2

K 121630

Non-cervical, non-pedicle spinal fixation devices intended for posterior or anterolateral thoracolumbar screw stabilization as an adjunct to fusion, in skeletally mature patients, for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Except for the ARI staples, the Range Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior noncervical fixation in pediatric patients. The Range Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

**7. Comparison of the technological characteristics of the device to predicate and legally marketed devices :**

The design features and sizing of the components were compared to predicate devices and the Range Spinal System was determined to be substantially the same as these systems.

**8. Comparison of the performance data of the device to predicate and legally marketed devices :**

The Range Spinal System implants were previously tested in static compression, static torsion and dynamic compression in accordance with ASTM F1717. The implants were determined to be substantially equivalent to predicate devices. Published clinical results for similar devices supported the safety and efficacy of these devices.

**9. Conclusion:**

There are no significant differences between the Range Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

P, 2 of 2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

June 27, 2013

K2M, Incorporated  
% Ms. Nancy Giezen  
Manager of Regulatory Affairs  
751 Miller Drive SE, Suite F1  
Leesburg, Virginia 20175

Re: K121630  
Trade/Device Name: Range Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: OSH, MNI, MNH, KWP  
Dated: August 6, 2012  
Received: August 7, 2012

Dear Ms. Giezen:

This letter corrects our substantially equivalent letter of September 11, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin D. Keith

For

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K121630

Device Name: Range Spinal System

**Indications for Use:**

RANGE/ DENALI/ MESA and ARI are cleared for the following indications:

Non-cervical, pedicle screw fixation devices for posterior stabilization as an adjunct to fusion for the following indications: trauma ( i.e. fracture or dislocation ); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis ( grades 3 and 4 ) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine ( L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Non-cervical, non-pedicle spinal fixation devices intended for posterior or anterolateral thoracolumbar screw stabilization as an adjunct to fusion, in skeletally mature patients, for the following indications: degenerative disc disease (DDD ) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies ); spondylolisthesis; trauma ( i.e. fracture or dislocation); spinal stenosis; curvatures ( i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Except for the ARI staples, the Range Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior noncervical fixation in pediatric patients. The Range Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.


Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use       
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number  K121630

P31081